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10/599,394	03/27/2007	Alastair Edwin McAuley	1171/45543/173-PCT-US	8072
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TREXLER, BUSHNELL, GIANGIORGI, BLACKSTONE & MARR, LTD. 105 WEST ADAMS STREET SUITE 3600 CHICAGO, IL 60603			EXAMINER LOUIS, LATOYA M	
			ART UNIT 3771	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptodocket@trexlaw.com

Office Action Summary	Application No. 10/599,394	Applicant(s) EDWIN MCAULEY ET AL.
	Examiner LaToya Louis	Art Unit 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 March 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,6,7,10-12 and 20-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6,7,10-12 and 20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. This office action is responsive to the amendment filed 3/23/2010. As per the amendment, claims 1, 2, 7, and 10-12 have been amended, claims 3, 5, 8, 9, and 13-19 have been cancelled, and claims 20-35 have been added. Thus claims 1, 2, 4, 6, 7, 10-12, and 20-35 are currently pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor or carrying out his invention.

3. Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 21-23, the limitation “the outer sealing member including a sealing flange” in claim 21 line 3 is not sufficiently supported in applicant’s original disclosure. Examiner has interpreted the “outer sealing member” to be equivalent to the sheath as disclosed on page 8 line 24 of applicant’s disclosure. However there is no disclosure of the sheath including a sealing flange that “has a reduced cross-sectional thickness compared with said peripheral wall” (claim 22 line 2) and that is “shaped to follow the contours of said peripheral ridge” (claim 23 line 2). Applicant has pointed to page 10, lines 19-23 for support for this

amendment however page 10 lines 19-23 recites “the inner flange 307 of the cushion 301...”

Thus only the inner cushion is disclosed as having a flange in this section. However if applicant interprets the outer sealing member of claim 21 to be equivalent to the inner cushion of applicant’s disclosure, then at least claims 7, 10, and 24 are unclear. For example, claim 10 recites "said inner cushion and said outer sealing member are continuously in contact" and claim 24 recites "an inner cushion arranged about said opening in the mask and adjacent the outer sealing member." Since only one cushion is disclosed in applicant's disclosure, it is unclear how the outer sealing member and the inner cushion could both be the inner cushion. It is also noted that another flange is disclosed on page 6 line 29 of applicant's disclosure however this flange belongs to the mask body and is separate from the sheath and the cushion and does not support the limitations of claims 22 and 23.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the limitation “the body section” on lines 9 and 10 lack antecedent basis.

Regarding claim 6, the limitation “the patient interface” lacks antecedent basis.

Claims 2, 4, 7, 10-12, and 20-24 are rejected for their dependency on a rejected claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6, 7, 10-12, and 20-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Palkon et al. (2003/0019495 A1).

Regarding claim 1, Palkon teaches in figs. 1, 3 and 6 a breathing assistance apparatus (10), comprising: a mask body (16) adapted to cover the nose of a patient, and a sealing interface; including at least an outer sealing member (membranes 46, 47, and 48 as outer sealing member. Alternatively only membrane 46 as outer sealing member), arranged about an opening (35) in the mask body, the outer sealing member including a peripheral wall (45) adapted to attach to the mask body section in a sealing manner ([0028] lines 6-14), the peripheral wall (45) including, a bridge region (45b) that extends over a patient's nasal bridge in use; the bridge region (45b) of said peripheral wall having a thinner cross- section than the rest of said peripheral wall (fig. 6 and [0029] lines 19-44) wherein said outer sealing member (46, 47, 48) is adapted to seal around the facial contours of a patient thereby providing a sealed fluid communication to the respiratory tract of said patient ([0011] and [0012]).

Regarding claim 2, Palkon discloses that the rest of the peripheral wall of the outer sealing member is at least twice the cross-sectional thickness of the bridge region ([0029] lines 19-44 disclose that the membrane 46b at the nasal bridge region has a thickness of about 0.02 in. while the membrane 46a at the lip region has a thickness of about 0.06 in.).

Regarding claim 6, Palkon teaches from fig. 1 that the patient interlace is a nasal mask.

Regarding claim 7, Palkon teaches that the sealing interface includes an inner cushion (30), the inner cushion has a raised section in the bridge region (As seen from figs. 3, 5, and 6, the inner cushion is raised in the nasal bridge region).

Regarding claim 10, Palkon teaches that the inner cushion (30), and the outer sealing member are continuously in contact (as seen from fig. 6, the membranes are continuously in contact with the cushion).

Regarding claim 11, Palkon teaches in fig. 3 that the inner cushion (30) includes a contoured region (40) that is positioned adjacent a patient's cheeks in use, the contoured region is concave and is capable of accommodate the cartilage extending away from the nose of a patient.

Regarding claim 12, Palkon teaches from figs. 3- 5 that the bridge region of the peripheral wall is tapered away from said patient with respect to the remainder of the peripheral wall.

Regarding claim 20, Palkon teaches in figs. 1-3 that the outer sealing member has a contacting portion (the raised portions of the outer portion 31 as contacting portion) that extends about the peripheral wall and is configured to contact a patient's face, the peripheral wall (45) of the outer sealing member extending between the mask body (16) and the contacting portion, the contacting portion shaped to approximately follow the contours of a patient's face.

Regarding claim 21, Palkon teaches from figs. 1-3 that the contacting portion is a peripheral ridge, the outer sealing member including a sealing flange (face engaging portion 33 as flange. Alternatively, lip portion 43 as flange) that extends inwardly from said

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peripheral ridge, the sealing flange configured to seal said breathing assistance apparatus against a patient's face (the face engaging portion as sealing flange engages a user's face to seal the apparatus against a user's face. Alternatively, the lip portion 43 as flange seals the cushion to the shell 15 which enables the cushion of the apparatus to be against a patient's face in use. See [0028] lines 6-11).

Regarding claim 22, Palkon teaches from figs. 3 and 6 that the sealing flange has a reduced cross-sectional thickness compared with said peripheral wall (the face engaging portion 33 as flange has a reduced cross-sectional thickness in at least the nasal bridge region as compared to the peripheral wall in the lip region. See [0030] lines 1-3 and [0029] lines 10-44. Alternatively, as seen from fig 6, the lip portion 43 as sealing flange has a reduced cross sectional thickness compared to the peripheral wall).

Regarding claim 23, Palkon teaches from figs. 1 and 3 that the sealing flange is shaped to follow the contours of said peripheral ridge (As shown in fig. 3, the face engaging portion 33 as flange follows the contours of the ridge. Alternatively, as shown in fig. 1, the lip portion 43 is molded around the base of the cushion to engage the cushion with the rim 17. Thus the lip portion follows the circular contour of peripheral ridge).

Regarding claim 24, Palkon teaches in figs. 1-3 an inner cushion (30) arranged about the opening (35) in the mask and adjacent the outer sealing member (46, 47, 48), the inner cushion in continuous contact with the outer sealing member at the contacting portion.

Regarding claim 25, Palkon teaches in figs. 1-6 a user interface comprising: a mask body (16), and a resilient sealing member (membranes 46, 47, and 48 as resilient sealing member) arranged about an opening (35) in the mask body, the sealing member comprising a peripheral

wall (45) that extends from the mask body, the wall including a bridge region (45b) that is positioned adjacent a user's nasal bridge in use, the bridge region having a reduced material thickness to permit the bridge region to deform sufficiently to accommodate a user's nose ([0029] lines 19-44).

Regarding claims 26 and 33, Palkon discloses that the material thickness of the bridge region is significantly less than the material thickness of adjacent portions of the peripheral wall ([0029] lines 19-44).

Regarding claims 27 and 34, Palkon discloses that the material thickness of the bridge region is significantly less than the material thickness of the remainder of the peripheral wall ([0029] lines 19-44)

Regarding claim 28, Palkon teaches a contacting portion (the raised portions of the outer portion 31 as contacting portion) configured to contact a user's face, the contacting portion extending about the peripheral wall.

Regarding claim 29, Palkon teaches that the resilient sealing member further comprises a sealing flange (33) configured to form a seal with a user's face, the sealing flange extending inwardly from the contacting portion.

Regarding claim 30, Palkon teaches that the contacting portion and the sealing flange are shaped approximately to a user's facial contours (figs. 1 and 2 and [0011]).

Regarding claim 31, Palkon teaches that the peripheral wall has a flattened base securing portion (32) configured engage with a complimentary securing track (rim 17) arranged about the opening in the mask body to secure the sealing member in place ([0028] lines 6-14).

Regarding claim 32, Palkon teaches in figs. 1-6 a sealing member (30) for a user

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interface comprising: a peripheral wall (45) arranged in a loop and configured to enclose a user's nose, the peripheral wall having a mask end (32) configured to engage with a respiratory mask and a user end (the face portion of outer portion 31 as user end) configured to contact a user's face ([0027]), and a sealing flange (32) arranged about the user end (33) of the peripheral wall and projecting inwardly of the closed loop, the sealing flange configured to seal against a user's face, the peripheral wall including a bridge region (45b) that is positioned adjacent a user's nasal bridge in use, the bridge region having a significantly reduced cross-sectional thickness ([0029] lines 19-44).

Regarding claim 35, Palkon teaches that a contacting ridge (the raised edges of outer surface 31 as sealing flange) is formed at an interface between the peripheral wall (45) and the sealing flange (32), the contacting ridge being shaped approximately to the contours of a user's face.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palkon.

Regarding claim 4, Palkon discloses a nasal mask (fig. 1) but does not specifically disclose that the patient interface is a full face mask. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient interface of Palkon to be a full face mask as such is old and well known in the art, well within the artisan's skill, and would require a mere change in size/length of the components. Further such a modification would perform equally well and is considered a design consideration.

Response to Arguments

11. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lithgow et al. (7,523,754 B2) discloses a cushion with outer membranes of thinner cross sectional thickness in the nasal bridge region and which is embodied as a full face mask.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya Louis whose telephone number is (571)270-5337. The examiner can normally be reached on Monday-Friday, 9:30am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LaToya Louis/
Examiner, Art Unit 3771
6/25/2010

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767